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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HARLE, JENNIFER I	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,962	BIERGIESSER ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565 or class 562, subclass 560, for example.

II. Claim19-20, drawn to a method for the prophylaxis or treatment of an inflammatory skin condition or for the protection of dry or sensitive skin by applying a cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565.

III. Claims 21-22, drawn to a method for treating the prophylaxis or treatment of the symptoms of intrinsic or extrinsic skin aging or of the harmful effect of ultraviolet radiation on the skin by applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

IV. Claims 23-24, drawn to a method for treatment or prophylaxis of environmentaly induced negative alterations of the skin or skin appendages by applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

V. Claim 25, drawn to a method for the treatment or prophylaxis of pigmentation disorders comprising applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

VI. Claims 26-27, drawn to a method for the treatment or prophylaxis of functional disorders of skin appendages comprising applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for exmaple.

VII. Claim 28, drawn to a method for the enhancement of hair growth comprising applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group

consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, form example.

VIII. Claim 29, drawn to a method for increasing ceramide biosynthesis comprising applying to the skin cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

IX. Claims 30-31, drawn to a method for strengthening the barrier function of the skin comprising applying cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

X. Claim 32, drawn to treatment or prophylaxis of disorders of the normal skin pH and of the osmolyte balance comprising applying to the skin cosmetic or dermatologic preparations with a content of an active ingredient combination of at least one compound selected from the group consisting of creatinine and derivatives thereof and at least one compound selected from the group consisting of creatine and derivatives thereof, classified in class 514, subclass 565, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a method for prophylaxis or treatment of dry or sensitive skin can be accomplished by utilization of a moisturizer or foundation; a method for the prophylaxis of treatment of the symptom of the harmful effects of ultraviolet radiation on the skin and a method for the treatment or prophylaxis of environmentally inducted negative alterations of the skin or skin appendages or pigmentation disorders can be accomplished by utilization of a sunscreen or cosmetic surgery; a method for the treatment or prophylaxis of functional disorders of the skin appendages, i.e. dandruff by use of dandruff specific shampoos; a method for the enhancement of hair growth by the use of various medication, i.e. Propecia, Rogaine, etc.; a method for increasing ceramide biosynthesis by the use of hydroxyacids (See US Patent 6,277,881); a method for strengthening the barrier function of the skin by the use, i.e. developing a skin care program, reducing stress and preventing irritations, i.e. scratching (See Atopic Dermatitis, National Institutes of Health and national Institute of Arthritis and Musculoskeletal and Skin Diseases, January 1999, pp. 1-22, see specifically pp. 4—5, 11-12, 16); a method for the treatment or prophylaxis of disorders of the normal skin pH and of the osmolyte balance by using a pH balanced skin cleanser.

3. Inventions II-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated 2) the material being used 3) the methodology for treatment. If any one or more of these difference exist and are patentably distinct, then the methods are unrelated. In the instant case the different methods of use invents are unrelated because the patient populations treated for each method is divergent For example a person skin inflammation, i.e. Group I presumes the patient being treated has an inflammatory condition, while treatment of symptoms of intrinsic or extrinsic skin aging, i.e. Group II presumes that the being treated is patient is old, while Group III presumes that the patient has been exposed to environmentally induced negative alterations of the skin or skin appendages and has nothing to do per se with inflammation or age of the patient and Group IV presumes that the patient has a pigmentation disorder and can be unrelated to either inflammation or age or environment, i.e. genetics; Group V presumes that the patient has a "functional" disorder of the skin appendages and speaks of dandruff, greasy skin, greasy hair and can be unrelated to inflammation or age or environment or a pigmentation disorder; Group VI presumes that the patient has hair loss, which can be unrelated to inflammation, age, environment pigmentation disorder or a "functional" disorder; each group has a set of different diseases that encompass different patient populations with different idiopathies and presume that the patient has that particular disease and is being treated for that disease.

4. Because these inventions are distinct for the reasons and impose a serious search burden on the examiner given the defined areas the plethora of different diseases, synonyms for the methods and the compositions including each derivative, different databases, search structures,

above and the search required for Group I-X are each other, restriction for examination purposes as indicated is proper.

5. Claims 1-16 and 19-32 are generic to a plurality of disclosed patentably distinct species comprising for Groups I and II:

a) creatinine derivatives

b) creatine derivatives

For Group II claim 19 is generic to another set of disclosed patentable distinct species comprising:

c) inflammatory skin conditions

d) sensitive or dry skin conditions

For Group III claim 21 is generic to another set of disclosed patentable distinct species comprising:

e) intrinsic or extrinsic skin aging

f) harmful effects of ultraviolet radiation on the skin

For Group IV claim 23 is generic to another set of disclosed patentable distinct species comprising:

g) environmentally induced negative alterations of the skin or skin appendages

For Group V claim 25 is generic to another set of disclosed patentable distinct species comprising:

h) pigmentation disorders

For Group VI claim 26 is generic to another set of disclosed patentable distinct species comprising:

i) prophylaxis of functional disorders of skin appendages

For Group IX claim 30 is generic to another set of disclosed patentable distinct species comprising:

j) strengthening the barrier function of the skin

For Group X claim 32 is generic to another set of disclosed patentable distinct species comprising:

k) disorders of the normal skin pH and of the osmolyte balance.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Where the examiner has required restriction between product and process claims and Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CRF 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the required for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 36 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of product and process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, not that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

February 11, 2005